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Docket No: 515-4218

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT OPERATIONS

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| In re Application of: | ) | |
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| **Achille Arini et al.** | ) | Group Art Unit: |
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| | ) | |
| Serial No.: 09/815533 | ) | Examiner: |
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| Filed: March 16, 2001 | ) | |
| | ) | |

For: **METHOD FOR THE PRODUCTION OF PHARMACEUTICALLY ACTIVE RECOMBINANT PROTEINS**

New York, N.Y. 10036
April 23, 2001

Commissioner For Patents
Washington, D.C. 20231

## INFORMATION DISCLOSURE STATEMENT

SIR:

Request is hereby made for consideration of this information disclosure statement. The following references are being cited under the provisions of § 1.97.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents
Washington, DC 20231

on April 23, 2001

James V. Costigan, Reg. No. 25,669

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| EP 0 154 272 B1 | Discloses the production of urokinase using recombinant DNA techniques which involve recovering mRNA from human kidney cells, preparing cDNA, inserting into a vector and introducing the resulting plasmid into an animal cell. |
| EP 0 303 028 A1 | Discloses a method for preparing single chain urokinase by recovering the prourokinase gene from human cells, inserting into a vector and introducing the plasmid into an animal cell. |
| DE 3439 980 A1 | Discloses a procedure for purifying and pasteurization of urokinase where the product can be used for therapeutic purposes. |
| DT 25 51 017 A1 | Discloses a procedure for the production of urokinase. |

NONPATENT LITERATURE

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| "Urinary and Kidney Cell Plasminogen Activator", G.H. BARLOW, *In* Scrip's Thrombolytic Report, pp. 239-245. | Describes urokinase assay methods using the Clot Lysis method and the Esterolytic method. Describes a purification methodology from urine or media and properties of urokinase. |
| "Plasminogen and Plasmin", K.C. ROBBINS & L. SUMMARIA, *In* Scrip's Thrombolytic Report, pp. 257-273. | Describes plasminogen/plasmin specificity and assay methods, nomenclature, method of isolation, isoelectric focusing, activation/ inhibition and properties. |

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| "N-Linked Carbohydrate Chains From Human Urokinase", A.A. BERGWERFF, 228 Eur. J. Biochem., 1009-19 (1995). | Describes the primary structure of the major N-linked carbohydrate chains attached to urinary-type plasminogen activator (urokinase). |
| "High Level Expression of Human Prourokinase cDNA in Chinese Hamster Ovary Cells", C. DUSHENG et al., 9(3) Chinese J. Biotech. 151-158 (1994). | Describes the expression of high levels of human prourokinase gene CDNA in Chinese hamster ovary cells, construction of good expression vector, improved transfection technique and gene co-amplification. |
| "Abbott Abbokinase Use Should be Limited Due to Infection Risks From Donors", F-D-C REPORTS, THE PINK SHEET, February 1, 1999, p.6. | Discusses the FDA "Dear Doctor" letter of 1/25/99 pertaining to the risk of infectious disease transmission from Abbokinase®. |

A copy of each of the above references is enclosed.

Respectfully submitted,

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